K052447

SEP 2 1 2005

510(k) SUMMARY
FOR
Analogic Corporation
SyneRad IMPACT 60, SyneRad IMpact 72 and Analogic AMS1600

Submitter's Name and Address

Submitter's Name:	Analogic Corporation
Address:	8 Centennial Drive
City, State, and Zip:	Peabody, MA, 01960

Contact Person

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Title:	Director of Regulatory Affairs
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Manufacturing Facility Address

Manufacturer:	Analogic Corporation
Address:	8 Centennial Drive
City, State, and ZIP:	Peabody, MA, 01960

Establishment Registration Number

Est. Registration Number:	1220672

New Device Details

Proprietary of Trade Names

Proprietary or Trade Name:	SyneRad IMPACT 60 SyneRad IMpact 72 and Analogic AMS1600

New Device Common Name

Common Name:	Computed Tomography X-ray system

New Device Class

Device Class:	Class II

New Device Product Code

Device Procode: 90JAK

New Device CFR

Device CFR: 892.1750

New Device Classification Panel

Classification Panel: Radiology

New Device Classification Name

Classification Name: System, X-ray, Tomography, Computed

Reason for submission

Reason for submission New Devices

Comparison with predicates

Predicate #1	K033502		GE Lightspeed 6.0 CT Scanner System
Predicate #2	K030420		GE Lightspeed 5.0 CT Scanner System
Predicate #3	K020385,	K022050	Toshiba Aquilion 16 CFX

Description of These Devices

The SyneRad IMPACT 60, SyneRad IMPACT 72 and Analogic AMS1600 Multislice Computed Tomography Systems consist of a gantry, a patient table and an operator console.

All three CT Systems are virtually identical. The physical size of all three systems is the same and they use the same control console, operating system and software. The Analogic AMS1600 is the platform from which the two Anexa systems are built and is identical in construction (except for cosmetics created by the covers) to the SyneRad IMpact 72. The difference between the SyneRad IMPACT 60 and the SyneRad IMpact 72 is the output rating of the High Voltage Power Supply mounted on the gantry. The SyneRad IMPACT 60 has a 60 kW PSU whereas the SyneRad IMpact 72 has a 72 kW PSU. The kVp levels are the same for both systems. The upper mA setting for the 60 kW system is 500 mA. The upper mA setting for the 72 kW system is 600 mA. The High Voltage Power Supply provides feedback to the control computer which selects the upper mA limit.

These 16-slice CT scanners have a gantry aperture opening of 70 centimeters. They are based on proven Analogic computed tomography technology. They have a 16-row detector and a 0.50 second minimum scan time. High-speed image reconstruction is from an innovative reconstruction engine. The operator console is supplied with two 20-inch high resolution monitors. 3D software is standard. Workflow and patient throughput requirements are supported by local archiving and DICOM-based interconnectivity features.

Summary of Intended Uses

The SyneRad IMPACT 60, SyneRad IMPACT 72 and Analogic AMS1600 are Computed Tomography X-ray Systems intended to produce images of the head and whole body by computer reconstruction of X-ray transmission data at different angle and planes. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.

Comparison of Technological Characteristics

The SyneRad IMPACT 60, SyneRad IMPACT 72 and Analogic AMS1600 Multislice Computed Tomography Systems utilize the same technological characteristics and operating principles, are comparable in key safety and effectiveness and QA features, and uses the same basic design, construction and materials.

They also have the same intended use and modes of operation (CT scanning throughout the whole body including Spiral, Axial, Dynamic, Scout modes, additional optional scan modes like CT fluoro and ECG gated acquisition). Their X-ray power and technique factors are comparable to the predicate devices. They also have comparable image quality performance (measured on phantoms) as the predicate devices. The control console displays weighted CTDI, Dose Length Product and geometric efficiency in a method similar to the predicate devices.

In the opinion of Analogic Corporation, the SyneRad IMPACT 60, SyneRad IMPACT 72 and Analogic AMS1600 are of comparable type and substantially equivalent to the currently marketed head and whole body X-ray computed tomography systems that comply with the same or equivalent standards and have the same intended use. These new devices will be certified to comply with the X-ray requirements of 21CFR1020.30 and 1020.33 as well as the safety requirements of UL 60601-1 and IEC 60601-1 and associated collateral and particular standards.

	Analogic		G. E. Healthcare		Toshiba
Model	SyneRad IMPACT 72	SyneRad IMPACT 60	LightSpeed 6.0 (LightSpeed Pro16)	LightSpeed 5.0 (LightSpeed 16)	Aquilion 16 CFX
K Number	New Devices		K033502	K030420	K020385 and K022050
Spiral, Axial, Dynamic and Scout Scanning	Yes	Yes	Yes	Yes	Yes
CT fluoro and ECG gated scan mode	Optional	Optional	Optional	Optional	Optional
kW output	72 kW	60 kW	100 kW	53.2 kW	60 kW
kVp Range	80, 100, 120, 140 kVp	80, 100, 120, 140 kVp	80, 100, 120, 140 kVp	80, 100, 120, 140 kVp	80, 100, 120, 135 kVp
mA Range	10 - 600 mA	10 - 500 mA	10 - 800 mA	10 - 440 mA	10 - 500 mA
High Contrast Spatial Res					
0% MTF, lp/cm	17.25 lp/cm	17.25 lp/cm	15.4 lp/cm	15.4 lp/cm	18 lp/cm
50% MTF, lp/cm	8+ lp/cm	8+ lp/cm	8.5 lp/cm	8.5 lp/cm	9.4 lp/cm
Low-contrast res., mm @ % @ 4 rads	5 mm @ 0.30%, 8" CATPHAN	5 mm @ 0.30%, 8" CATPHAN	5 mm @ 0.30%, 8" CATPHAN	5 mm @ 0.30%, 8" CATPHAN	5 mm @ 0.3% @ 21.8 mGy (per MHRA)
Weighted CTDI shown on console	Yes	Yes	Yes	Yes	Yes
Dose Length Product shown on console	Yes	Yes	Yes	Yes	Yes
Geometric Efficiency displayed on console when < 70%	Yes	Yes	Yes	Yes	Yes

Key Parameters Comparison Chart

Compliance with Voluntary Standards

Before final market release, the SyneRad IMPACT 60, SyneRad IMPACT 72 and Analogic AMS1600 Multislice Computed Tomography Systems will be thoroughly validated at the unit and system level to meet all elements of its Requirements Specification. This includes the following non-clinical tests:

Standards No.	Standards Organization	Standards Title	Version	Date
60601-1-1	IEC	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	2	2000
60601-1	IEC	Medical Electrical Equipment- Part 1: General Requirements for Safety	2 +A1, +A2	1988, 1991, 1995
60601-1	UL	Medical Electrical Equipment- Part 1: General Requirements for Safety	1	2003
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	2	2001
60601-1-3	IEC	Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	1	1994
60601-2-32	IEC	Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	1	1994
60601-2-44	IEC	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography	2.1	2002

Conclusion

Based on similarity in technology, characteristics and the same intended use as the predicates, and compliance with the Radiological Safety Regulations supported by bench testing, Analogic Corporation considers the SyneRad IMPACT 60, SyneRad IMPACT 72 and the Analogic AMS1600 substantially equivalent.

Bench testing demonstrates that the SyneRad IMPACT 60, SyneRad IMPACT 72 and the Analogic AMS1600 comply with 21CFR Subchapter J.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Analogic Corporation
c/o Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K052447
Trade/Device Name: SyneRad Impact 60 and 72, and Analogic AMS1600
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 6, 2005
Received: September 7, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K052447

Device Name: SyneRad IMPACT 60 and SyneRad IMpact 72 and Analogic AMS1600

Indications For Use: The SyneRad IMpact 60, SyneRad IMpact 72 and Analogic AMS1600 are Computed Tomography X-ray Systems intended to produce images of the head and whole body by computer reconstruction of X-ray transmission data at different angle and planes. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.

Prescription Use (Per 21 CFR 801 Subpart D) X ~~AND~~/OR Over-The-Counter Use (Per 21 CFR 801 Subpart C) ____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052447